UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,158	02/23/2004	Martin C. Hinz	3364.25US-01	8497

24113 7590 01/22/2007

PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,158	HINZ, MARTIN C.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-35 and 37-53* is/are pending in the application.

4a) Of the above claim(s) *11,16-18,21-23,28-32 and 46-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,12-15,19,20,24-27,33-35,37-45 and 51-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4-35 and 37-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 30 October 2006 have been entered. Claims 3 and 36 are canceled; claims 1 – 2, 4 – 35, and 37 – 53 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Claims 11, 16 – 18, 21 – 23, 28 – 32, 46 – 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 May 2006.

4. Claims 1 – 2, 4 – 10, 12 – 15, 19 – 20, 24 – 27, 33 – 35, 37 – 45, and 51 – 53 are under examination.

Withdrawn Rejections and Objections

5. The following rejections and objections set forth in the previous office action are withdrawn:

A. The objection to claim 1 is withdrawn in light of the amendment.

B. The rejection of claims 1, 4 – 9, 15, 20, and 27 under 35 USC 112, second paragraph are withdrawn in light of the amendments. The amendments clarify the scope of patent protection sought.

C. The rejection of claim 33 under 35 USC 112, second paragraph for lack of antecedent basis is withdrawn in light of the amendment.

D. The rejections under 35 USC 102(b) over Curtius et al. (U.S. 4,774,244) are withdrawn in light of the amendments. Curtius does not teach administration of "an amino acid precursor of a neurotransmitter to the subject", which is now required by claim 1.

Maintained Rejections

Claim Rejections - 35 USC § 112

6. Claims 12 – 14, 19, 24 – 26, 33 – 45, and 51 – 53 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On p. 12 of the remarks, applicant states that claim 12 has been amended to clarify how a neurotransmitter is both serotonin and catecholamine. While claim 12 has the status identifier "(Currently amended)", no amendments have actually been made to the claim, so rejection of record stands.

On p. 13 of the remarks, applicant argues that "baseline reference point" (recited in claim 13) and "reference range" (recited in claim 14) are exemplified in the specification. While they are exemplified, the terms are not explicitly defined in a closed-ended manner. They are replete with ambiguity and whether or not a point is within "a reference range" for example is entirely in the mind of the artisan. It is not possible to tell what the metes and bounds of claims 13 – 14 are, because the ranges themselves are indefinite. Thus the rejection claims 13 – 14 stands. Similarly, claim 19 recites "an optimal range" which is not explicitly defined in the specification for all possible neurotransmitters. While certain values are defined for serotonin, dopamine, norepinephrine, and epinephrine, claim 19 is not limited to any particular neurotransmitter or any particular disease or condition. Thus the "optimal range" for neurotransmitters other than those defined in the specification is unclear, so the scope of claim 19 is unclear. Claims 24 – 26 also recite "a reference range" and "a therapeutic point", and these terms are not explicitly defined in the specification. Note that the specification specifically states on p. 17 that "these numbers are a relative guide only... the therapeutic range should not be fixed on the absolute numbers reported." Thus the rejection stands.

The amendment to claim 33 clarifies the scope of what is to be graphed, but as claim 33 depends from claim 25 which is indefinite, claim 33 stands rejected as well. Applicant argues that "inflection point", recited in claims 34 – 35, is defined in the specification. While it is mentioned in the text, it is not actually defined. The skilled artisan could not determine what actually constitutes "an inflection point", especially if the curve is flat or if the slope does not change. The specifications does not tell the artisan how "the inflection point is used to determine the therapeutic range". While certain therapeutic ranges are mentioned in the specification, the specification fails to teach the artisan how to use the point, which is itself undefined, to determine what the range actually is. Therefore the rejections of claims 33 – 36 stand for the reasons of record.

Claim 37 has been amended so that the assay is performed on a body fluid, rather than administered to a body fluid; this clarifies the scope of the claim somewhat. However, the claim still recites "a predetermined therapeutic range" which is indefinite, even though certain ranges

are recited in an exemplary fashion. Note that only certain neurotransmitters are identified in the specification, and the specification specifically teaches the artisan that the numbers are "a relative guide only". Thus the claim remains ambiguous because it is unclear what constitutes "a predetermined therapeutic range of neurotransmitter levels." Furthermore, the claim is slightly unclear because it recites "performing a first assay of a body fluid"; amending to "on a body fluid" is recommended for the sake of clarity. Claims 38 – 45 stand rejected because they depend from claim 37. While the amendments to claims 28 – 41 clarify the language of those claims, since they depend from claim 37, which is ambiguous as set forth above, they are also rejected.

Claim 51 stands rejected because, as with claim 33, it remains ambiguous what constitutes an inflection point and how said point is used to determine the therapeutic range. Claim 52 depends from claim 51 and fails to further clarify these ambiguities. Claim 53 remains ambiguous for the reasons stated previously and above; it is unclear what constitutes "a baseline neurotransmitter level", "a predetermined therapeutic range", "an inflection point", and how said point is to be used to determine the therapeutic range.

Claim Rejections - 35 USC § 102

7. Claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 37 – 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross (1999. The Diet Cure, of record).

This rejection stands for the reasons of record and explained in further detail herein. Note that claim 1 has been amended to require administration, however this limitation is provided for in the reference and had previously appeared in claim 37. Briefly, Ross teaches treatments for excessive weight, which is reasonably the same as obesity. The treatments comprise administering amino acids to humans. Ross further teaches that prior to administration, testing should be done.

Ross provides a rather thorough list of amino acid and neurotransmitters to be tested and administered. See the table spanning pp. 120 – 121. Note that while in certain cases the amino acids are distinct from the related neurotransmitter, in other cases the two are identical. For example, the neurotransmitter GABA is also an amino acid as it comprises an amino group and a carboxy group (GABA stands for "gamma amino butyric acid"). Note further that Ross explicitly teaches measuring amino acid levels; see the paragraph spanning pp. 128 – 129. Since GABA is a neurotransmitter which is also an amino acid, and the reference by Ross

clearly teaches testing amino acids and administering them for treatment of obesity, it reasonably meets the limitations of independent claims 1 and 37.

Applicant argues, on p. 16 of the remarks that:

1) Ross does not teach assaying the neurotransmitter level to determine a neurotransmitter status point, and

2) Ross does not teach administering an amino acid precursor for neurotransmitters. Applicant's arguments have been fully considered but they are not persuasive. As explained above, Ross teaches "testing for amino acid levels". As some of the amino acids described in Ross are in fact neurotransmitters (i.e. GABA), the reference clearly teaches assaying neurotransmitter levels. Once the level has been obtained, it is reasonably a "neurotransmitter status point", even though Ross does not use that exact language. With respect to point 2) above, Ross clearly does teach administering a plethora of amino acid precursors for neurotransmitters. See p. 117 which states "use amino acid supplements to correct your brain chemistry", and the table spanning pp. 120 – 121. Note that column C of the table denotes which amino acid is to be administered, and column D indicates which neurotransmitter the amino acid is a precursor for. Thus Ross clearly teaches all elements of independent claims 1 and 37.

Applicant did not traverse the examiner's determination that the reference meets every limitation of the dependent claims subject to this rejection, beyond stating that the rejection should be withdrawn as it does not apply to the independent claims. Therefore the rejection of claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 37 – 39, and 41 stands.

Claim Rejections - 35 USC § 103

8. Claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ross.

This rejection stands for the reasons of record. Applicant did not traverse the examiner's determination that "graphing the neurotransmitter level over time" as recited in claim 33 would have been obvious to one of ordinary skill in the art but rather argued that Ross does not anticipate claim 1. However as set forth above, Ross does in fact anticipate claim 1, so this rejection stands as well.

9. Claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, 41 – 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ross as applied to claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, and 41 above, and further in view of Curtius et al. (U.S. Patent 4,774,244, issued 27 September 1988).

This rejection stands for the reasons of record. Applicant did not traverse the examiner's determination that the subject matter of claims 42 – 43 would have been obvious to one of ordinary skill in the art but rather argued that Ross does not anticipate independent claim 37. However as set forth above, Ross does in fact anticipate claim 37, so this rejection stands as well.

Rejections and Objections Necessitated by Amendment

Claim Rejections - 35 USC § 112

10. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendments to claim 10 make it ambiguous. The claim now requires that "the neurotransmitter is a neurotransmitter of the serotonin system." It is unclear whether the scope of this claim is limited to serotonin, which is reasonably the only neurotransmitter of the serotonergic system, or whether it includes other neurotransmitters as well, and if so what those other neurotransmitters might be. Thus the skilled artisan could not determine the metes and bounds of the patent protection sought.

Claim Rejections - 35 USC § 103

11. Claims 1 – 2, 4 – 5, 7, 10, 12 – 14, 19, 24 – 26, 33, 37 – 39, and 41 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross.

The reasons why Ross either anticipates or renders obvious claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, and 41 – 43 are set forth in the rejections under 35 USC §§ 102 and 103 above. While Ross teaches that serotonin is involved in obesity and the levels should be modulated to control weight and overeating (see for example p. 123), the reference does not explicitly teach assaying serotonin as recited in claims 12 and 44.

It would have been obvious to one of ordinary skill in the art to measure serotonin levels, as recited in claims 12 and 44. The motivation to do so would be to determine the serotonin

levels. This motivation comes directly from the reference by Ross, who teaches assaying for substances associated with obesity, such as amino acids, and teaches that serotonin levels often have to be boosted for treatment of weight gain. Note Ross states that a patient should "take a 250- to 1,000-milligram dose of L-tryptophan" in order to boost serotonin levels (top of p. 123). By determining assaying for serotonin levels, the artisan of ordinary skill would be able to determine which dosage should be administered.

12. Claims 1 – 2, 4 – 5, 7 – 9, 10, 23 – 14, 19, 24 – 26, 33, 37 – 39, and 41 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross in view of Curtius et al. (U.S. Patent 4,774,244, issued 27 September 1988).

The reasons why Ross either anticipates or renders obvious claims 1 – 2, 4 – 5, 7, 10, 12 – 14, 19, 24 – 26, 33, 37 – 39, and 41 – 44 are set forth in the rejections under 35 USC §§ 102 and 103 above. However Ross does not teach collecting urine for assay 5 – 6 hours before bedtime, as recited in claim 8, or measuring micrograms of neurotransmitter per gram of creatinine as recited in claim 9.

Curtius teaches measurement of serotonin in the urine of a patient with inhibited depression (see Table 1). Curtius also teaches that urine samples were collected at 0, 2, 4, 8 – 10, and 12 hours. While the reference is silent as to the patient's bedtime and the actual time of collection, any one of these points reasonably falls 5 – 6 hours before the patient's bedtime. For instance, if the patient's bedtime is 11PM, and the first sample is collected at 9 AM, then 8 – 10 hours later is 5PM – 7 PM, which is within the range of 5 – 6 hours before the bedtime and is on point to claim 42. The results are expressed in umoles of neurotransmitter per mole of creatinine (see table). While this is not "per gram of creatinine" as recited in claim 43, the values are easily converted and said conversion does not distinguish the invention of claim 43 from the prior art.

It would have been obvious to one of ordinary skill in the art to modify the method of Ross and obtain a urine sample 5 – 6 hours before the subject's bedtime, as taught by Curtius. The motivation to do so would be to select a time point that is convenient to the subject and allows for accurate measurement of the neurotransmitter. It would also be obvious to measure the neurotransmitter in micrograms of neurotransmitter per gram of creatinine, as Curtius teaches it is appropriate to normalize to creatinine levels, and converting from umoles per mole to micrograms per gram is a trivial mathermatical operation.

Note that this rejection is necessitated by applicant's amendments to claims 1 and 7 and therefore does not constitute a new grounds of rejection.

13. Claims 1 – 2, 4 – 7, 10, 12 – 14, 19, 24 – 26, 33, 37 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross as applied to claims 1 – 2, 4 – 5, 7, 10, 12 – 14, 19, 24 – 26, 33, 37 – 39, and 41 – 44 above, and further in view of Marukawa (1996. Headache 36:100-104).

The reasons why Ross either anticipates or renders obvious claims 1 – 2, 4 – 5, 7, 10, 12 – 14, 19, 24 – 26, 33, 37 – 39, and 41 – 44 are set forth in the rejections under 35 USC §§ 102 and 103 above. However, Ross does not explicitly teach measuring neurotransmitters in saliva, as recited in claims 6 and 40.

Marukawa teaches that several amino acids, including substance P, GABA, and serotonin (also referred to as "5-HT" by Marukawa; note this is a commonly-accepted abbreviation for serotonin) in saliva. See specifically p. 101, which teaches collection and preparation of salivary samples as well as measurement of all three neurotransmitters in the salivary samples. However Marukawa does not teach administration of amino acid precursors of neurotransmitters.

It would have been obvious to one of ordinary skill in the art to modify the method of Ross to measure the neurotransmitter levels in saliva, as taught by Marukawa, with a reasonable expectation of success. The motivation to do so would be to more easily obtain samples. While Ross teaches collection of samples of bodily fluids, saliva is not named as one of them. But due to the non-invasive nature of collecting saliva, as well as a subject's ability to produce a sample essentially on-demand, collecting samples via this route would offer considerable advantages over collecting blood or urinary samples. Marukawa further provides the reasonable expectation of success, as the reference teaches measurement of three separate neurotransmitters from saliva.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker
January 16, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER